REMARKS

This Response is submitted in reply to the non-final Office Action mailed on October 21, 2008. A one-month extension fee is submitted herewith. The Commissioner is hereby authorized to charge any other fees that may be required or credit any overpayment to the Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-722 on the account statement.

Claims 1-3 and 5-19 are pending in the application. Claim 4 was previously canceled. Claims 12-19 were previously withdrawn from consideration. In the Office Action, Claims 1-3 and 5-11 are rejected under 35 U.S.C. §101 and 35 U.S.C. §112; Claims 1, 2 and 3 are rejected under 35 U.S.C. §102, and Claims 1 and 5-11 are rejected under 35 U.S.C. §103. In response, Applicants have amended Claims 1-3 and 5-11, the amendments supported in the specification at page 2, lines 1-2; page 4, lines 37-38. In view of the amendments and for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-3 and 5-11 are rejected under 35 U.S.C. §101 for being directed to non-statutory subject matter. Specifically, the Office Action asserts that the claimed recitation of use is non-statutory. In response, Applicants have amended independent Claim 1 to recite a method for manufacturing an oral composition to treat the effects of infection caused by enterotoxin-producing pathogens, the method comprising: adding 0.01% to 0.5% yeast extract by volume to an oral composition. Moreover, Claims 2-3 and 5-11 have been amended to depend from the method of Claim 1. As amended, Claim 1 provides the method step of adding an amount of a particular component, yeast extract, to an oral composition to treat the effects of infection caused by enterotoxin-producing pathogens.

Applicants submit that the present claims are directed to statutory subject matter. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

In the Office Action, Claims 1-3 and 5-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the claims fail to point out what is included or excluded by the claim language. Specifically, the Office Action asserts that Claim 1 is vague and indefinite for the recitation of "use of yeast extract" and that dependent Claims 2-3 and 5-11 are vague and indefinite for their recitation of "The use of claim 1." In view of the amendments to

Claims 1-3 and 5-11 discussed above, particularly the removal of "use" language from all the present claims, Applicants submit that Claims 1-3 and 5-11 meet the requirements under 35 U.S.C. §112, second paragraph. Applicants accordingly request that this rejection be withdrawn.

In the Office Action, Claims 1, 2 and 3 are rejected under 35 U.S.C. §102(b) as being anticipated by Japanese Patent Publication 2001-055338 to Tomohiko, et al. ("*Tomohiko*") as evidence by Mims, et al., (Medical Microbiology, 3rd edition, 2004, pp. 277-289) ("*Mims*"). Amended independent 1 recites a method for manufacturing an oral composition to treat the effects of infection caused by enterotoxin-producing pathogens, the method comprising: adding 0.01% to 0.5% yeast extract by volume to an oral composition. Applicants respectfully submit that *Tomohiko* fails to disclose or suggest every element of the rejected claims.

Applicants submit that *Tomohiko* fails to disclose or suggest a method for manufacturing an oral composition, the method comprising: adding 0.01% to 0.5% yeast extract by volume to an oral composition. By contrast, the machine translation of *Tomohiko* states that the preferred solid concentration of the yeast-fungus object is 5-20 weight %, with the yeast-fungus object slurry more preferably adjusted to about 10 weight %. See, *Tomohiko* (machine translation), [0012]. In fact, each of the examples in *Tomohiko* teach post-fermentation brewer's yeast slurry diluted with water such that the solid content of the slurry becomes 10 weight %. See, *Tomohiko* (machine translation), [0020-0026]. United States equivalent application (U.S. Publication No. 2002/0155126) confirms the yeast-cell slurry range as well as the 10 weight % taught in Preparations 1-6. See, U.S. Publication No. 2002/0155126, [0025 and 0033-0045].

Moreover, after a yeast-cell fraction is extracted from the yeast-cell slurry discussed above, the yeast-cell fraction is still added to a consumable composition at a concentration significantly above the 0.01% to 0.5% yeast extract by volume required in the present claims. It should be noted that the machine translation of *Tomohiko* fails to translate Tables 1-9. However, based upon the Japanese translation of yeast ("酵母"), it was apparent that the tables of compositions indicated yeast-cell wall fraction concentrations of between 5% and 10% of the composition. See, *Tomohiko*, Tables 3, 6 and 9. Further, U.S. Publication No. 2002/0155126 confirms the above 5% and 10% concentrations of yeast-cell wall fraction in the compositions, as shown below:

TABLE 3

<Foodstuff Composition>

	Control Group	Yeast Cell Wall Fraction Group
Casein	14.6	11.8
AIN93 Mineral Mixture	3.5	3.5
AIN93 Vitamin Mixture	1	1
Starch	67	65.5
Corn Oil	5	5
Cellulose	5.7	—
2nd Preparative Example of Yeast Cell Wall Fraction	—	10
Dextran Sulfate Sodium	3	3
Choline Chloride	0.2	0.2
TOTAL	100	100

TABLE 6

(Foodstuff Composition)

	Control Group	Raffinose Group	Yeast Cell Wall Fraction Group
Casein	20	20	17
DL-methionine	0.3	0.3	0.3
Corn Starch	54	54	53
Sucrose	10	10	10
Cellulose Powder	6	—	—
Corn oil	5	5	5
AIN93 Mineral Mixture	3.5	3.5	3.5
AIN93 Vitaine mixture	1	1	1
Bitartrate Choline	0.2	0.2	0.2
Raffinose	—	6	—
Yeast Cell Wall Fraction	—	—	10
TOTAL	100	100	100

TABLE 9

(Foodstuff Composition)

	Control Group	Yeast Cell Mall Fraction Group
Casein	14.6	13.5
AIN93 Vitamin Mixture	1.0	1.0
AIN93 Mineral Mixture	3.5	3.5
Choline Chloride	0.2	0.2
Cellulose	2.9	—
Yeast Cell Wall Fraction	—	5.0
Loperamide Hydrochloride	0.01	0.01
Corn Oil	5.0	5.0
Corn Starch	72.79	71.79
TOTAL	100	100

Therefore, Applicants submit that *Tomohiko* is deficient with respect to amended independent Claim 1. Accordingly, Applicants request that the anticipation rejection of Claims 1-3 be withdrawn.

In the Office Action, Claims 1 and 5-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Tomohiko* in view of U.S. Publication No. 2005/0244392 to Pei, et al. ("*Pei*"). As stated above, *Tomohiko* fails to disclose or suggest a method for manufacturing an oral composition, the method comprising: adding 0.01% to 0.5% yeast extract by volume to an oral composition as required, in part, by amended independent Claim 1.

Applicants submit that *Pei* fails to remedy the deficiencies of *Tomohiko*. *Pei* is directed to the use of new probiotic strains and new Lactobacillus strains for the prophylaxis or treatment against digestive, infective, neuro-degenerative and immune related diseases such as allergies or inflammatory diseases. See, *Pei*, Abstract. Rather than disclosing use of yeast for beneficial purposes, *Pei* teaches yeasts as a cause of chronic/acute infection or undesirable microbial colonization. *Pei* also teaches the use of lactic bacteria to produce bioactive peptides components and other metabolites that selective inhibit the growth of other bacteria, yeast or fungi. See, *Pei*, Claim 20 and [0150]. In fact, the Office Action relies of *Pei* arguably to disclose oral compositions comprising peptones and meat extracts, rather than the yeast extracts of the present claims.

Therefore, both *Tomohiko* and *Pei* fail to disclose or suggest a method comprising: adding 0.01% to 0.5% yeast extract by volume to an oral composition as required, in part, by amended independent Claim 1. Applicants accordingly request that the obviousness rejection of Claims 1 and 5-11 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit and early allowance of same.

Respectfully submitted,

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